DEC - 4 2009 K091672

Section 3 **510(k) Summary**

As required by 807.97

The assigned 510(k) Number is _____

Sponsor	Shuyou Electric Medical Science Co., Ltd. Anji Economic Development Zone Health(medicine) Industrial Park ,Huzhou ,Zhejiang,China, 313300 Ms. Wei Liu Tel:+86-572-5300005 ext. 801 Fax: +86-572-5300004 Email: shuyou_china001@sina.com
Submission Correspondent	Ms. Diana Hong / Mr. Tarzan Wang Shanghai Mid-Link Business Consulting Co., Ltd Sute 8D, No.19, Lane 999, Zhongshan No.2 Road(S) Shanghai, 200030, China Tel: +86-21-64264467 Fax: 240-238-7587 Email: diana.hong@mid-link.net
Proposed Product	
Trade Name	Disposable Grounding Pad series/ Disposable Electrode series
Product Code:	GEI
Regulation Number:	21 CFR 878.4400
Device Class:	Class II
Submission Purpose:	New Device
Predicate Device:	Skintact Cool Contact Electrosurgical Grounding Plates (K063161) E-Z Clean electrosurgical electrodes (K081791)
Test Conclusion	The Disposable Grounding Pad and Disposable Electrode are designed, tested and will be manufactured in accordance with both mandatory and voluntary standards, including: IEC 60601-1, Medical Electrical Equipment – Part 1: General

	Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995. IEC 60601-2-2, Medical Electrical Equipment – Part 2-2: Particular requirements for the safety of high frequency surgical equipment.
SE Determination	The proposed device is **Substantially Equivalent (SE)** to the predicate device which is US legally market device. Therefore, the subject device is determined as safe and effectiveness.
Intended Use/Indication for Use	The Disposable Grounding Pad series devices are to conduct electrosurgical energy from target tissue of a patient back to an electrosurgical unit (ESU), or generator. The Disposable Electrode series devices are intended to conduct radio frequency (RF) current for cutting and coagulation from the electrosurgical generator to target soft tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DEC - 4 2009

Shuyou Electric Medical Science Co., Ltd.
% Shanghai Mid-Link Business Consulting Co., Ltd.
Ms. Diana Hong, General Manager
Suite 8D, No. 19, Lane 999, Zhongshan No. 2 Road(S)
Shanghai, 200030, China

Re: K091672
Trade/Device Name: Disposable Grounding Pad Series and Disposable Electrode Series
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI, ODR
Dated: November 13, 2009
Received: November 17, 2009

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

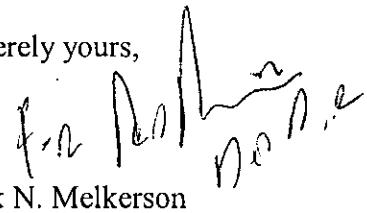
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication For Use

510(k) Number (if known): ___Pending_____

Device Name: __Disposable Grounding Pad Series____

Indications for Use:

The Disposable Grounding Pad series devices are to conduct electrosurgical energy from target tissue of a patient back to an electrosurgical unit (ESU), or generator.

Prescription Use ___√_____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091672

Indication For Use

510(k) Number (if known): Pending

Device Name: Disposable Electrode Series

Indications for Use:

The Disposable Electrode series devices are intended to conduct radio frequency (RF) current for cutting and coagulation from the electrosurgical generator to target soft tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091672